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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,291	02/07/2002	Yoshiki Takashima	Q68127	1132

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EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 06/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/067,291

Applicant(s)

TAKASHIMA ET AL.

Examiner

Elizabeth Slobodyansky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24-26 is/are allowed.
- 6) ☒ Claim(s) 23 and 27-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/527,522.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

The amendment filed April 14, 2003 (Paper No. 5) canceling claims 5-22 and adding claims 23-34 has been entered.

Claims 23-34 are pending.

Election/Restriction

Applicant's election without traverse of Group I, claims 5-16, in Paper No. 5 is acknowledged. New claims 23-34 encompass the subject matter of Group I.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119 (a)-(d). The certified copy has been filed in parent Application No. 09/527,522, filed on March 16, 2000.

Information Disclosure Statement

The instant application contains no IDS.

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Specification

The disclosure is objected to because of the following informalities: there is heading "BRIEF DESCRIPTION OF THE DRAWINGS" wherein there are no drawings in the specification (page 15, line 15).

Appropriate correction is required.

The abstract of the disclosure is objected to because it is non-descriptive with regard to the instant invention. Amending the abstract similarly to the parent application is suggested.

Claim Objections

Claim 34 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

In the interest of compact prosecution claim 34 was construed as drawn to a method for producing a protein which converts acetophenone to an optically active 1-phenylethylamine in the presence of a racemic mixture of sec-butylamine comprising culturing the transformant of claim 29 or transformant of claim 30.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23 and 27-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 23(d) is drawn to a DNA encoding "an amino acid sequence having 60% or greater identity to SEQ ID NO:1" and having no functional limitations.

The specification does not contain any disclosure of the structure and function of DNAs encoding proteins that derived from SEQ ID NO:1 and have an amino acid sequence at 60% identical thereto or having unknown percent identity thereto. The genus of DNAs that comprise these above DNA molecules is a large variable genus with the potentiality of encoding proteins having many different functions. Therefore, DNAs encoding many structurally and functionally unrelated proteins are encompassed within the scope of these claims, including partial sequences. The specification discloses only a single species of the claimed genus, a DNA encoding a specific stereoselective transaminase from *Mycobacterium* having the amino acid sequence of SEQ ID NO:1. Moreover, the specification fails to describe any other representative

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species by any identifying characteristics or properties and fails to provide any structure: function correlation present in all members of the claimed genus. Therefore, the specification is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Claims 27-34 are rejected as dependent from claim 23.

Claims 23 and 27-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a protein of SEQ ID NO:1, does not reasonably provide enablement for a DNA encoding a protein with unknown function having an amino acid sequence that is 60% identical to SEQ ID NO:1 as well for a DNA encoding a specific transaminase having an amino acid sequence that is 60% or 80% identical to SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, how to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4)

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the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) considered in determining whether undue experimentation is required, are summarized the predictability or unpredictability of the art, and (8) the breadth of the claims.

Claim 23(d) is directed to a DNA encoding a protein from any source with unknown activity having an amino acid sequence that is 60% identical to SEQ ID NO:1.

Claim 23(f) is directed to a DNA encoding a protein from *Mycobacterium* with a specific transaminase activity having an amino acid sequence that is 60% identical to SEQ ID NO:1.

Claim 23(e) is directed to a DNA encoding a protein from any source with a specific transaminase activity having an amino acid sequence that is 80% identical to SEQ ID NO:1 and a molecular weight of about 37 kDa as a monomer.

The specification does not support the broad scope of the claims which encompass any transaminase with wide substrate specificity because the specification does not establish: (A) regions of the protein structure which may be modified without effecting the specific requisite activity of the polypeptide of the instant invention; (B) the general tolerance of said polypeptide to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residues with an expectation of obtaining the desired biological function; and (D) the specification

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provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Despite knowledge in the art to produce mutations in proteins, the specification fails to provide guidance as to where, and what type of (i.e., what amino acid to substitute into, add to or delete from the known sequence), changes in amino acid residues will result in a desired enzymatic activity. The amino acid sequence of a protein determines its structural and functional properties, and predictability of what mutations can be tolerated in a protein's sequence and result in a certain activity is extremely complex, and well outside the realm of routine experimentation, because accurate predictions of a protein's function from mere sequence data are limited.

Furthermore, while recombinant and mutagenesis techniques are known, it is not routine in the art to screen large numbers of mutated proteins or genes where the expectation of obtaining similar activity is unpredictable based on the instant disclosure.

Claim 23 (d) encompasses DNAs encoding proteins with the requisite transaminase activity and proteins of unknown function. Without knowing the function of the protein one of skill in the art would not have known how to use it.

Therefore, one of ordinary skill in the art would require guidance, in order to make a DNA encoding a specific transaminase having an amino acid sequence 60% or 80% identical to SEQ ID NO:1 and to use a DNA encoding a protein of unknown

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function having an amino acid sequence 60% identical to SEQ ID NO:1 in a manner reasonably correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

Allowable Subject Matter

Claim 24-26 are allowed.

The examiner notes that "an amino acid substitution" in claim 23(b) was construed as "a single substitution". Amending the claim to recite "a single substitution" will be consistent with the language of the parent case and is suggested.

Claim 24(b) and claim 26 were construed as reciting the sequence that differs from SEQ ID NO:2 by a single substitution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.


Elizabeth Slobodyansky, PhD
Primary Examiner